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Dated: 2-24-05 Signature: Maura A. Gallagher  
(Paula Depollean)  
Maura A. Gallagher

Docket No.: CWRU-P03-003  
(PATENT)

IFW

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Sanford D. Markowitz

Application No.: 10/649,591

Confirmation No.: 4997

Filed: August 26, 2003

Art Unit: 1645

For: METHODS AND COMPOSITIONS FOR  
CATEGORIZING PATIENTS

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Copies of the references on the PTO/SB/08 are not provided because they were previously cited by or submitted to the Office in a prior application number 10/229,345, filed August 26, 2002 and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this


Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

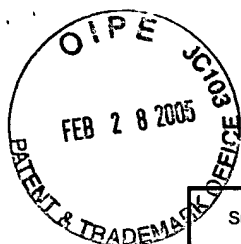
The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. CWRU-P03-003.

Dated: February 24, 2005

Respectfully submitted,

By   
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PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
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<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/649,591		
		Filing Date	August 26, 2003		
		First Named Inventor	Sanford D. Markowitz		
		Art Unit	1645		
		Examiner Name	Not Yet Assigned		
Sheet	1	of	2	Attorney Docket Number	CWRU-P03-003

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	AA	WO 99/38881	08-05-1999	Human Genome Sciences Inc.		
	AB	WO 01/75067	10-11-2001	Hyseq, Inc.		
	AC	WO 01/90357	11-29-2001	Genesis Res. Dev. Corp.		
	AD	WO 02/21996	03-21-2002	EOS Biotechnology, Inc.		
	AE	WO 02/30268	04-18-2002	EOS Biotechnology, Inc.		
	AF	WO 02/50301	06-27-2002	Gene Logic, Inc. et al.		
	AG	WO 02/068677	09-06-2002	EOS Biotechnology et al.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AH	Alon, U. et al. Broad patterns of gene expression revealed by clustering analysis of tumor and normal colon tissues probed by oligonucleotide arrays. PNAS 96, 745-6750 (June 1999).	
	AI	Bieller, A. et al. Isolation and Characterization of the Human Forkhead Gene FOXQ1. DNA Cell Biol. 20, 555-561 (2001).	
	AJ	Deng, G. et al. Methylation of CpG in a Small Region of the hMLH1 Promoter Invariably Correlates with the Absence of Gene Expression. Cancer Res. 59, 2029-2033 (1 May 1999).	
	AK	Esteller, M. et al. Detection of Aberrant Promoter Hypermethylation of Tumor Suppressor Genes in Serum DNA from Non-Small Cell Lung Cancer Patients. Cancer Res. 59, 67-70 (1 January 1999).	
	AL	GenBank Accession No. W07459 (25 April 1996).	
	AM	GenBank Accession No. AI357412 (06 Jan. 1999).	
	AN	GenBank Accession No. AI590539 (9 April 1999).	
	AO	GenBank Accession No. AI870708 (21 July 1999).	
	AP	GenBank Accession No. BAA92054 (16 Feb. 2000).	
	AQ	GenBank Accession No. AY007815 (29 Aug. 2000).	
	AR	GenBank Accession No. AAG41062 (29 Aug. 2000).	
	AS	GenBank Accession No. XM_061091 (31 July 2002).	
	AT	Hardy, R.G. et al. Aberrant P-cadherin expression is an early event in hyperplastic and dysplastic transformation in the colon. Gut 50, 513-514 (2002).	
	AU	Herman, J.G. et al. Incidence and functional consequences of hMLH1 promoter hypermethylation in colorectal carcinoma. PNAS 95, 6870-6875 (June 1998).	
Examiner Signature			Date Considered

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
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				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	CWRU-P03-003

AV	Hibi, K. et al. Molecular Detection of Genetic Alterations in the Serum of Colorectal Cancer Patients. <i>Cancer Res.</i> 58, 1405-1407 (1 April 1998).	
AW	Kane, M.F. et al. Methylation of the hMLH1 Promoter Correlates with Lack of Expression of hMLH1 in Sporadic Colon Tumors and Mismatch Repair-defective Human Tumor Cell Lines. <i>Cancer Res.</i> 57, 808-811 (1 March 1997).	
AX	Kobayashi, A. et al. Molecular Cloning and Functional Characterization of a New Cap'n' Collar Family Transcription Factor Nrf3. <i>J. Biol. Chem.</i> 274, 6443-6452 (5 March 1999).	
AY	Markowitz, S. et al. Inactivation of the Type II TGF- $\beta$ Receptor in Colon Cancer Cells with Microsatellite Instability. <i>Science</i> 268, 1336-1338 (1995).	
AZ	Radice, G.L. et al. Precocious Mammary Gland Development in P-Cadherin-deficient Mice. <i>J. Cell Biol.</i> 139, 1025-1032 (17 Nov. 1997).	
BA	Scott, D.A. et al. Refining the DFNB7-DFNB11 deafness locus using intragenic polymorphisms in a novel gene, TMEM2. <i>Gene</i> 246, 265-274 (2000).	
BB	Shimoyama, Y. et al. Molecular Cloning of a Human Ca <sup>2+</sup> -dependent Cell-Cell Adhesion Molecule Homologous to Mouse Placental Cadherin: Its Low Expression in Human Placental Tissues. <i>J. Cell Biol.</i> 109, 1787-1794 (1989).	
BC	Unigene Hs.157601, Homo sapiens transcribed sequences.	
BD	Veigl, M.L. et al. Biallelic inactivation of hMLH1 by epigenetic gene silencing, a novel mechanism causing human MSI cancers. <i>PNAS</i> 95, 8698-8702 (July 1998).	
BE	Weber, G.F. The metastasis gene osteopontin: a candidate target for cancer therapy. <i>Biochim. Biophys. Acta.</i> 1552, 61-85 (2001).	
BF	Wines, M.E. et al. Identification of Mesoderm Development (mesd) Candidate Genes by Comparative Mapping and Genome Sequence Analysis. <i>Genomics</i> 88-98 (2001).	
BG	Wong, I.H.N. et al. Detection of Aberrant p16 Methylation in the Plasma and Serum of Liver Cancer Patients. <i>Cancer Res.</i> 59, 71-73 (1 Jan. 1999).	
BH	Zhang, J.-S. et al. Keratin 23 (K23), a Novel Acidic Keratin, Is Highly Induced by Histone Deacetylase Inhibitors During Differentiation of Pancreatic Cancer Cells. <i>Genes Chromosomes Cancer</i> 30, 123-135 (2001).	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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